



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



January 10, 2012

Senator John A. Alario, Jr., President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804

Re: Report No. 1 of 3 for Regulatory Project 2011-1 ~ Pharmacist-in-Charge (PIC) Requirements
Report No. 1 of 3 for Regulatory Project 2011-2 ~ Cognitive Services
Report No. 1 of 3 for Regulatory Project 2011-7 ~ Penal Pharmacy
Report No. 1 of 3 for Regulatory Project 2012-1 ~ E-Communications
Report No. 1 of 3 for Regulatory Project 2012-2 ~ Hospital Pharmacy
Report No. 1 of 3 for Regulatory Project 2012-3 ~ Remote Processing of Medical Orders

Dear Senator Alario:

The Board has initiated the rulemaking process to amend six different sections of its rules. For each of the six projects identified above, you should find the following documents in this packet:

- Insertion Order for the Louisiana Register
- Notice of Intent
- Proposed Rule
- Fiscal & Economic Impact Statement
- Regulatory Flexibility Analysis
- Family Impact Statement

As indicated in the notice, we will convene a public hearing on February 28, 2012 to receive testimony and public comments on these proposals. We will summarize those comments and our responses thereto in our next report to you. If you have any questions or need additional information, please contact me directly at 225.925.6481 or mbroussard@pharmacy.la.gov.

For the Board:

Malcolm J. Broussard
Executive Director

OFFICE OF THE STATE REGISTER INSERTION ORDER (effective 8/2000)
Claiborne Building 1201 North Third Street Suite 3-220 Post Office Box 94095
Baton Rouge, LA 70804-9095 (225)342-5015 FAX (225)342-0284

RECEIVED

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OFFICE OF THE STATE REGISTER

(SUBMIT A SEPARATE INSERTION ORDER PER DOCUMENT)

- EMERGENCY RULE NOTICE OF INTENT RULE POTPOURRI

REFER TO INSTRUCTIONS ON REVERSE SIDE

This is your authority to publish in the (month) January, 2012 *Louisiana Register* the document indicated above.

Board of Pharmacy
Office/Board/Commission promulgating this document

Malcolm J Broussard Executive Director
(name) (title)
Name and title of person whose signature will appear in the publication (at the end of the document)

Health and Hospitals
Department under which office/board/commission is classified

Malcolm J Broussard 225.925.6481 225.922.0316
(name) (phone) (fax)
Name, phone number, and FAX number of person to contact regarding this document
mbroussard@pharmacy.la.gov
E-mail address of contact person

Provide a short descriptive listing for this document to be used in the *Louisiana Register's* TABLE OF CONTENTS/INDEX (note: this description should match the fiscal statement title, if sending a Notice of Intent:

*If sending a diskette, indicate the name of the file on diskette:

Remote Processing of Medical Orders

Important: If submitting both an Emergency Rule (ER) and a Notice of Intent (NOI) to be published this month, AND if the rule text in the ER is identical to the rule text in the NOI, check here:

Malcolm J Broussard
Signature of Agency Head or Designee
Malcolm J Broussard, Executive Director
Print Name and Title of Agency Head or Designee

CERTIFICATION OF AVAILABLE FUNDS DOCUMENT # _____

ISIS AGENCY: I certify the availability of fiscal year _____ appropriated funds for the payment of the above referenced publication and authorize the processing of an Interagency Billing with the following coding on the 30th of the month of the publication. Attach supplemental sheet for additional lines of coding.

AGENCY ORGANIZATION # OBJECT SUB-OBJECT REPORTING CATEGORY

NON-ISIS AGENCY: I certify the availability of fiscal year 11-12 appropriated funds for the payment of the above referenced publication and agree to place corresponding invoice in line for payment upon receipt.

Billing Address for Agencies:
Louisiana Board of Pharmacy
Agency Name
3388 Brentwood Drive
Street Address or Post Office Box
Baton Rouge LA 70809
City State Zip Code

Malcolm J Broussard 225,925,6481
Signature of Agency Head or Designee - Phone #

Lines/Other Charges _____ Typesetting \$ _____ TOTAL \$ _____

Notice of Intent

Department of Health and Hospitals Board of Pharmacy

Remote Processing of Medical Orders

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend two sections of its rules relative to the remote processing of medical orders. In particular, the proposed amendments will permit hospital pharmacies to engage in the remote processing of medical orders at any time during the day.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding these proposed amendments. A public hearing on these proposed amendments is scheduled for Tuesday, February 28, 2012 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

* * *

§1143. Remote Processing of Medical Orders or Prescription Drug Orders

A. General Requirements

* * *

2. ~~With respect to hospital pharmacies and institutional pharmacies,~~ A contract or agreement for remote processing services shall not relieve the on-site pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services ~~within the hospital or institutional facility.~~ The activities authorized by this Section are intended to supplement ~~hospital and institutional~~ pharmacy services ~~when the pharmacy is not operating~~ and are not intended to eliminate the need for an on-site pharmacy or pharmacist.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), amended LR

* * *

Chapter 15. Hospital Pharmacy

* * *

§1525. Remote Processing of Medical Orders (repealed)

~~A. General Requirements~~

- ~~1. A hospital pharmacy may obtain remote processing services from a remote processor provided the pharmacies:~~

- a.—~~Have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and~~
 - b.—~~Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.~~
- 2.—~~A contract or agreement for remote processing services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this Section are intended to supplement hospital pharmacy services when the pharmacy is not operating and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.~~

B.—~~Access to Patient Information~~

- 1.—~~The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the hospital pharmacist has access to when the pharmacy is operating. The remote pharmacist shall receive training in the use of the hospital's electronic systems.~~
- 2.—~~If a hospital pharmacy is not able to provide remote electronic access to the patient information system, both pharmacies shall have appropriate technology to allow access to the required patient information.~~

C.—~~Policies and Procedures~~

- 1.—~~Hospital pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall also be available for inspection and copying by the board.~~
- 2.—~~At a minimum, the manual shall include policies and procedures for:~~
 - a.—~~Identification of the responsibilities of each of the pharmacies;~~
 - b.—~~Protection of the integrity and confidentiality of patient information; and~~
 - e.—~~Maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such services.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), repealed LR

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing
Statement: **Malcolm J. Broussard**
Executive Director

Dept.: **Health and Hospitals**
Office: **Board of Pharmacy**

Phone: **(225) 925-6481**

Title: **Remote Processing of
Medical Orders**

Return Address:
**3388 Brentwood Drive
Baton Rouge, LA 70809-1700**

Date Rule
Takes Effect: **June 1, 2012 (est.)**

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

It is estimated that implementation of the proposed rule will cost the agency \$500 in FY 11-12, for printing costs.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

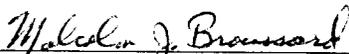
We can discern no measurable impact on revenue collections for state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

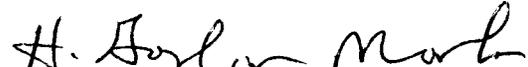
The proposed amendments will permit hospital pharmacies to engage in the remote processing of medical orders at any time of the day, instead of the current restriction to when one of the pharmacies is closed for the day. To the extent that the expansion of remote processing services require any additional software or hardware costs or provide any additional economic benefits to the hospital pharmacy from a reduced number of pharmacists, then the proposed amendment could increase those costs or economic benefits. However, the fiscal impact from this rule is not anticipated to be significant because it merely increases the number of hours per day a pharmacy could use such services. The Board is unable to estimate or quantify any such costs or benefits, as they will depend on the current status and needs of each pharmacy.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

We can discern no measurable effect on competition or employment in this state.



Signature of Agency Head or Designee



Legislative Fiscal Officer or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee

1-4-2012

Date of Signature

December 20, 2011

Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board proposes to amend one rule and repeal another, both relative to the remote processing of medical orders. The effect of the amendments will be to repeal the section of rules in the hospital pharmacy chapter relative to remote processing and then amend the section of rules applicable to all pharmacies to eliminate the current restriction on hospital pharmacies. A copy of the Notice of Intent is appended.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

In response to stakeholder input, the Board believes it reasonable to discontinue the disparity between community and hospital pharmacies relative to the opportunity to engage in the remote processing of medical orders at any time of the day. The current rules do not permit hospital pharmacies to engage in such practices when both pharmacies are open and operating. Among other effects, the current rule prohibits the opportunity for high intensity workloads at one hospital pharmacy to be distributed to other pharmacies with lower intensity workloads.

- C. Compliance with Act II of the 1986 First Extraordinary Session:

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

We can discern no measurable impact on the Board's expenditures, other than the printing costs of promulgation.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) ____ Yes. If yes, attach documentation.

(b) ____ No. If no, provide justification as to why this rule change should be published at this time.

The Legislature has not appropriated the funds. The Board of Pharmacy operates purely on self-generated funds, and the Board has sufficient funds budgeted and available for the promulgation process.

- D. Compliance with Act 820 of the 2008 Regular Session

(1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of 'small businesses,' we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. However, we can estimate the number using a specific classification of pharmacy permits; in particular, we do not believe the number of impacted small businesses would exceed 600.

(2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

There are no reporting requirements or costs associated with the proposed rule.

(3) A statement of the probable effect on impacted small businesses.

We can discern no measurable effect on small businesses from the proposed rule.

(4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

We can discern no alternative methods of achieving the same purpose of the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 500	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 500	\$ 0	\$ 0
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

We anticipate the printing costs for the implementation of the proposed rule to approximate \$500 (\$250 for the notice of intent and the same amount for the final rule).

3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 500	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 500	\$ 0	\$ 0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board currently has sufficient funds budgeted and available to complete the promulgation process.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

We can discern no impact on local governmental units.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
TOTAL	\$ 0	\$ 0	\$ 0

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

We can discern no impact on revenue collections of state and local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The persons directly affected by the proposed amendments are hospital pharmacies. Current rules permit community and hospital pharmacies to engage in the remote processing of medical orders; while community pharmacies may engage in such practices at any time of the day, hospital pharmacies are restricted to times when one of the pharmacies is closed for the day. The proposed amendments will repeal the existing rule in the hospital pharmacy chapter, and then amend the existing rule in the general pharmacy chapter so that any pharmacy can engage in the remote processing of medical orders at any time of the day.

To the extent any hospital pharmacy incurs costs for the remote processing of medical orders or derives any economic benefits from such activities, then the proposed amendments could increase those costs or economic benefits. We are unable to estimate those costs or benefits.

Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

We are not able to estimate any impact on receipts or income resulting from this proposed rule.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

We can discern no measurable impact on competition or employment in the public or private sectors.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

December 20, 2011
Date of Signature

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard**
Executive Director
Telephone: (225) 925-6481
Return Address: 3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Dept.: **Health and Hospitals**
Office: **Board of Pharmacy**
Title: **Remote Processing of
Medical Orders**
Date Rule Takes Effect: **June 1, 2012 (est.)**

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

There are no reporting requirements associated with the proposed amendments.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no deadlines for reporting requirements associated with the proposed amendments.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

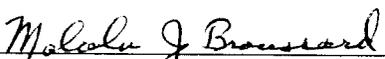
There are no reporting requirements associated with the proposed amendments.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design or operational standards in the proposed amendments.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

The proposed amendments will permit hospital pharmacies to engage in the remote processing of medical orders at any time of the day. There are no requirements relative to small businesses in the proposed amendments; therefore, no exemptions were considered.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee

December 20, 2011

Date of Signature

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard**
Executive Director

Dept.: **Health and Hospitals**
Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**
Title: **Remote Processing of
Medical Orders**

Return Address: **3388 Brentwood Drive**
Baton Rouge, LA 70809-1700

Date Rule Takes Effect: **June 1, 2012 (est.)**

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

We can discern no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

We can discern no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

We can discern no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

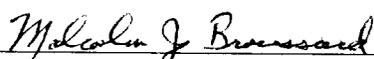
We can discern no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

We can discern no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

We can discern no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee

December 20, 2011

Date of Signature